

### **REMARKS**

Claims 1-28 are pending. Claims 1, 2, 6, and 8 are amended. Claims 12-28 are withdrawn. Support for the claims as amended is found throughout the specification, and no new matter is added.

#### **Objection to the Specification**

The Office Action states that the specification is objected to because it contains an embedded hyperlink on page 17. Applicants have amended the specification herein to remove the hyperlink and request that the objection be reconsidered and withdrawn.

#### **Rejection of Claims 1-6 and 8-11 Under 35 U.S.C. §102(b)**

The Office Action states that claims 1-6 and 8-11 are rejected as anticipated by Oberg et al. The Office Action states that Oberg et al. teaches a method of diagnosing colon cancer in an individual by detecting the presence of TIMP1, and further teaches diagnosing colon cancer by detecting the additional colon cancer markers MMP-2, MMP-9, and TIMP-2. Applicants respectfully disagree and traverse the rejection.

It is well established, black-letter law that to anticipate a claim, a prior art reference must teach each element of the claim, either expressly or inherently. *Atlas Powder Company et al. v. IRECO, Incorporated et al.*, 190 F.3d 1342, 1347 (Fed. Cir. 1999).

While not acquiescing to the rejection as applied to the claims as originally filed, Applicants have nonetheless amended the claims to recite a method of diagnosing colon cancer by detecting the presence of TIMP1 and Reg1 $\alpha$  in a sample, and optionally an additional colon cancer-specific marker. Oberg et al. does not teach the detection of both TIMP1 and Reg1 $\alpha$  and, as such, does not teach each limitation of the claimed invention. Thus, Oberg et al. does not anticipate the amended claims and Applicants request that the rejection be reconsidered and withdrawn.

**Rejection of Claims 1-6 and 8-11 Under 35 U.S.C. §102(e)**

*Pan et al.*

The Office Action states that claims 1-5 are rejected as anticipated by Pan et al. The Office Action states that Pan et al. teach a method of diagnosing colon cancer by detecting human TIMP1 in a serum sample using a TIMP1 antibody. Applicants respectfully disagree and traverse the rejection.

Without acquiescing to the rejection as applied to the claims as originally filed, Applicants have nonetheless amended the instant claims to require the detection of both TIMP1 and Reg1 $\alpha$ . Pan et al. does not teach or even suggest the combined detection of TIMP1 and Reg1 $\alpha$  and, therefore, does not teach each element of the claimed invention. Pan et al. provides no teaching or guidance that would suggest to one of skill in the art to combine the detection of TIMP1 with Reg1 $\alpha$  in a method for the detection of colon cancer. Accordingly, Pan et al. does not anticipate the claimed invention and Applicants request that the rejection be reconsidered and withdrawn.

*Holten-Andersen et al.*

The Office Action states claims 1-6 and 8-11 are rejected as anticipated by Holten-Andersen et al. The Office Action states that Holten-Andersen et al. teach a method for diagnosing colon cancer by detecting TIMP1 in serum samples and optionally determining the concentration of a second colon cancer tumor marker, such as CEA. Applicants respectfully traverse the rejection.

Without acquiescing to the rejection as applied to the claims as originally filed, Applicants have nonetheless amended the claims to recite a method of diagnosing colon cancer that requires the detection of both TIMP1 and Reg1 $\alpha$ , and optionally a second colon cancer-specific marker, such as CEA. Holten-Andersen et al. does not teach a method of detecting colon cancer by detecting TIMP1 and Reg1 $\alpha$ . Holten-Andersen does not teach or even suggest the detection of colon cancer using a combination of TIMP1 and Reg1 $\alpha$ . Specifically, the additional colon cancer markers taught by Holten-Andersen et al. are limited to CEA, soluble u-

PAR, cathepsin B, cathepsin H, HER2-neu, CA15-3, YKL-40, 19.9 and CA242. There is no teaching or guidance in Holten-Andersen that would suggest to one of skill in the art to combine TIMP1, Reg1 $\alpha$ , and at least CEA in a colon cancer detection method; Holten-Andersen et al. does not even mention Reg1 $\alpha$ . Holten-Andersen et al. does not teach each element of the claimed invention and, therefore, does not anticipate the claimed invention. Applicants request that the rejection be reconsidered and withdrawn.

**Rejection of Claims 6 and 7 Under 35 U.S.C. §103(a)**

The Office Action states that claims 6 and 7 are rejected under §103 as being unpatentable over Holten-Andersen et al. in view of Schrewe et al. The Office Action states that Holten-Andersen et al. teach a method of detecting colon cancer by detecting TIMP1 and a second colon cancer marker such as CEA. The Office Action states that Schrewe et al. teach the sequence of CEA having 100% identity to SEQ ID NO: 72. The Office Action concludes that it would have been obvious to detect the presence of CEA having the sequence of SEQ ID NO: 72 as a second colon cancer marker in addition to TIMP1. Applicants respectfully traverse the rejection.

As stated above, Holten-Andersen et al. fails to teach or even suggest a method of diagnosing colon cancer by detecting the presence of TIMP1 and Reg1 $\alpha$ , and optionally an additional colon cancer-specific marker such as CEA. There is no teaching or suggestion in Schrewe et al. that remedies this deficiency. Accordingly, even if combined, the teachings of Holten-Andersen et al. and Schrewe et al. do not teach each aspect of the claimed invention and, thus, do not render the amended claims obvious. Applicants, therefore, request that the rejection be reconsidered and withdrawn.

Applicant submits that all claims are allowable as written and respectfully request early favorable action by the Examiner. If the Examiner believes that a telephone conversation with Applicant's attorney/agent would expedite prosecution of this application, the Examiner is cordially invited to call the undersigned attorney/agent of record.

Respectfully submitted,

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Name: Matthew Beaudet

Registration No.: 50,649

Customer No.: 21874

Edwards Angell Palmer & Dodge LLP

P.O. Box 55874

Boston, MA 02205

Tel. (617) 239-0100